

Amendments to the Specification

Please break up in separate paragraphs the original paragraph spanning pages 5 and 6 as follows:

According to a particular embodiment of the process of the present invention, a ~~solution~~ mixture containing 0.01% to 5% of a surfactant agent, 0.1% to 5% of a lipophilic compound, wherein said lipophilic compounds are selected from among a group comprising of lycopene, beta-carotene, lutein, alfa-carotene, astaxanthin, zeaxanthin, vitamin A, vitamin E, vitamin D, omega 3, and omega 6 oils, or mixtures thereof, and 0% to 20% of a filler is prepared. Said ~~solution~~ mixture is processed for size reduction of the particles of the lipophilic compounds. Wherein the lipophilic compound is in solid form said solid ~~solution~~ mixture is processed in a grinder and wherein the lipophilic compound is in liquid form said ~~solution~~ mixture is processed in a high shear mixer. The processing of the lipophilic compound with a surface active agent (surfactant) creates a coating of the surfactant around the particles of the lipophilic compound, i.e. a primary protective layer.

_____ Following size reduction, a separate alkali metal alginate solution is prepared by dissolving an alkali metal alginate in water to provide a solution containing 0.5% to 10% of an alkali metal alginate, preferably 1.5% sodium alginate

in water. The alkali metal alginate solution is mixed with the ~~solution-mixture~~ containing the lipophilic compound. The resulting ~~solution-mixture~~ is homogenized to provide a substantially homogenous emulsion or dispersion which is added drop-wise to a solution containing 0.2% to 5% of Ca^{2+} , preferably 1.5% calcium chloride.

_____The drop-wise addition is carried out such that the drops are not bigger than 1000 μm . Thus, upon contact of the drops with the Ca^{2+} solution, beadlets of lipophilic-compound-containing alginate is formed. This creates a second protective layer for the lipophilic compound. The size of the beadlets can be controlled by controlling the size of the droplets. Preferably the size of the drops is adjusted so as to provide beadlets in the size range of about 100 μm to 450 μm .

_____The beadlets are ~~than~~ then separated from the ~~solution-liquid~~ by conventional separating means, e.g. screening, and rinsed with an aqueous acidic solution. The acidic solution is preferably a 0.1 to 10% solution of an acid selected from among a group comprising of citric, aspartic, acetic, ascorbic, lactic, phosphoric or hydrochloric acid. More preferably, said acidic solution is a 2.5% solution of citric acid or phosphoric acid in water. The rinsing with an acidic solution effects shrinkage of the beadlets and improves

the bioavailability of the microencapsulated lipophilic compound.

_____The beadlets are then dried according to drying methods known in the art, preferably, by fluidized bed drying.

"Drying" meaning lowering the water content below 10%.

_____The dry beadlets are then coated with a coating material in a fluidized bed apparatus, according to the coating technique described in U.S. Patent No. 4,710,384, incorporated herein by reference. Hence, a third coating layer is provided. Suitable coating materials for the final coating stage are cellulose derivatives, waxes, fats, proteins or polysaccharides. Non-limiting examples of cellulose derivatives suitable for coating material are: ethyl cellulose, hydroxy propyl cellulose, hydroxy propyl methyl cellulose and methyl cellulose. Waxes can be carnauba wax, candelilla wax and beeswax. Fats can be hydrogenated vegetable oils, e.g. soybean and palm oil, mono and diglycerides, stearic, palmitic acids. Proteins can be albumins, zein, soy proteins or milk proteins. Polysaccharides can be starches, maltodextrins, pectins, xanthan gum, gum Arabic or carrageenan. According to a particular embodiment of the present invention, wherein there is no restriction regarding the use of products derived from animals, gelatin may be applied as a suitable protein for the third layer coating.

Page 7, second paragraph, lines 4-9:

According to a particular embodiment of the present invention when the lipophilic compound is in liquid form, stage (i) of the process is carried out so that the drop size of the lipophilic compound is reduced to a size not greater than 20 μm , preferably in the range of 3 μm to 7 μm , and the ~~solution-mixture~~ obtained from stage (i) is an emulsion or suspension.

Paragraph spanning pages 8 and 9:

The present invention is advantageous in that it provides microcapsules of lipophilic compounds with improved stability, relatively high content of the lipophilic compound and improved bioavailability of the lipophilic compound. These advantages are achieved by the process which provides a three layer coating of the lipophilic compound and by the small particle size of said compounds. The advantages of the present composition are also found ~~it-in~~ the improved mechanical properties of the microcapsules which ~~is-are~~ are achieved by the third layer coating. Thus, the microcapsules of the present invention are also tablet grade, i.e. suitable for use in tableting. Furthermore the compositions of the present invention are gelatin free. Due to the fact that the common use of gelatin is obviated according to the present

invention, the product of the present invention is from vegetable origin.

Paragraph spanning pages 9 and 10:

~~The two solution~~ Suspension (a) and solution (b) were mixed together to form a homogenous suspension. The suspension was fed through a dispenser, installed above a 1.5% Calcium chloride solution in water. The spherical droplets, upon entering the solution, gel to form Beta-Carotene alginate matrix beads when retained in the solution for 5 to 30 minutes. The beadlets were collected by filtration and washed in 2.5% citric acid in water. The beadlets were dried and then coated in a fluidized bed dryer and coater. The coating material was made from the following ingredients:

(c)

- | | |
|---------------------------|-----------|
| 1. Hydroxypropylcellulose | - 70.0g. |
| 2. Methanol | - 177.0g. |
| 3. Acetone | - 369.0g. |

This process yielded coated dry spherical beads containing encapsulated β -Carotene. The particle size of 85% of the beads was between 150 microns and 425 microns.

Page 10, last paragraph:

A second solution was made at 70°C:

(b)

Appln. No. 09/935,050
Amd. dated May 9, 2005
Reply to Office Action of December 9, 2004

- | | |
|-----------------------|-----------|
| 1. Sodium Alginate | - 180.0g. |
| 2. Sucrose palminate | - 22.7g. |
| 3. Starch (from Peas) | - 120g |
| 4. Water | -12000.0g |

~~Solution~~ Mixture (a) was added to solution (b) and mixed to form a homogenous suspension.